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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,737	01/03/2007	Stephane Rioux	484112.436USPC	4671

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/568,737	RIOUX ET AL.	
	Examiner	Art Unit	
	Padma V. Baskar	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *23,36 and 38-42*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached note below.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645

/Padma Baskar/

Detailed Action

1. The after final amendment filed on 7/21/09 is entered.

Status of Claims

2. Claims 1-22,24-35, 37 and 43-48 have been cancelled
Claims 23, and 38-42 have been amended
Claims 23, 36, and 38-42 are under examination.

3. In view of cancelation of claims 21, 24, 37 and 43 and amendment to claim 42 , The new matter rejection of claims under 35 U.S.C. 112, first paragraph is withdrawn.
Claim Rejections - 35 USC 112, first paragraph
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 23, 36, 38, 40 and 42 are rejected under 35 U.5.C. 112, first paragraph for the reasons set forth below:

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (see MPEP 2163).
Claims 23, 36, 38, 40 and 42 are drawn to immunogenic composition or a kit comprising isolated polypeptide that consists of an amino acid sequence at least 90% or 95% identical to the full length acid sequence set forth as SEQ. ID. NO: 2, wherein the isolated polypeptide elicits an antibody that specifically binds to a polypeptide that consists of the amino acid sequence set forth as SEQ ID NO: 2. Claims are also drawn to an isolated polypeptide hat comprises an antigenic fragment-.that consists of at least 15 contiguous amino acids of SEQ ID NO:2, and wherein the antigenic fragment elicits an antibody that specifically binds to a polypeptide that consists of the amino acid sequence set forth as SEQ ID NO:2, and wherein the antigenic fragment induces an immune response against Streptococcus pyogenes.

Recitation of "90% or 95% or antigenic fragment of at least 15 contiguous amino acids of SEQ. ID. NO: 2 are viewed as variants/fragments of SEQ. ID. NO: 2". Thus, the scope of the claims includes a genus of polypeptides and the genus is highly variant, inclusive to numerous structural variants because a significant number of structural differences between genus members is permitted. The specification teaches a single polypeptide set forth as SEQ. ID. NO: 2. The specification does not place any structure, chemical or functional limitations on the variants/fragments embraced by "90% or 95% polypeptides of SEQ. ID. NO: 2. The recitation of said polypeptide or chimeric polypeptide does not convey a common structure or function and is not so defined in the specification. The specification and the claim do not provide any guidance on the structure of the polypeptide and what changes can or can not be made. "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., Eli Lilly.
Further, it is not sufficient to define it solely by its principal biological property, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. Per the Enzo court's example, (Enzo Biochem, Inc. v. Gen-Probe Inc., 63 USPQ2d 1609 (CA FC 2002) at 1616) of a description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) couched "in terms of its function of lessening inflammation of tissues" which, the court stated, "fails to distinguish any steroid from others having the same activity or function" and the expression "an antibiotic penicillin" fails to distinguish a particular penicillin molecule from others possessing the same activity and which therefore, fails to satisfy the written description requirement. Similarly, the function of variants/fragments "eliciting antibody and binding to full length SEQ.ID.NO:2 and wherein the antigenic fragment induces an immune response against Streptococcus pyogenes." does not distinguish a particular "variant/fragment" polypeptide from others having the same activity or function and as such, fails to satisfy the written-description requirement. Applicant has not disclosed any relevant, identifying characteristics, such as structure or other physical and/or chemical properties, sufficient to show possession of the claimed genus. Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required. A description of what a material does, rather than what it is, usually does not suffice. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
Structural features that could distinguish variants/fragments in the genus from others in the polypeptide class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus of SEQ.ID.NO;2 that function equivalently. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. Since the disclosure does not describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant, the function of the genus of "variants/fragments of SEQ.ID.NO:2" is unclear. One of skill in the art would reasonable conclude that the disclosure of a single polypeptide, i.e., SEQ ID NO: 2, does not provide a representative number of species of SEQ ID NO: 2 to describe the claimed genus. The recitation of "recitation of "90% or 95% or antigenic fragment of at least 15 contiguous amino acids of SEQ ID NO: 2" does not convey a common structure nor a common function (i.e., immune response against Streptoococcus pyogenes) As such, generic polypeptide sequences that are unrelated via structure and function are highly variant and not conveyed by way of written description by the specification at the time of filing. As such the specification lacks written description for the highly variant genus of single polypeptide and one skilled in the art would not recognize that applicants had possession of the genus of claimed polypeptides as instantly claimed.

Therefore, only the polypeptide set forth as SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant 7/21/09 states that instant claims satisfy the written description requirement and cites MPEP 2163. Applicant argues that SEQ.ID.NO:2 , the sequence that is 90% identical to SEQ.ID.NO:2 and fragments have been disclosed in the specification , pages 16, 18, 19, 48 . Working example 8 and 9 show that SEQ ID NO:2/ SHB-GAS 102 induces antibody response and animals were protected against challenge upon passive immunization of antibodies.
Applicants arguments are fully considered but has not been found persuasive because as applicant correctly states that SEQ ID NO:2/ SHB-GAS 102 has been shown to induce antibodies and protected animals upon transfer of antibodies to animals. However, structural features that could distinguish the claimed variant polypeptides in the genus from others in the protein class are missing from the disclosure and the claims. Further, the specification fails to correlate the structure /function relationship of representative number of species of polypeptides and/or an isolated polypeptide that is 90% or 95% identical to SEQ.ID.NO:2 induce an immune response against S. pyogenes .

6. Claims 23, 36, 38, 40 and 42 are rejected under 35 U.5.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising or consisting of the amino acid sequence set forth as SEQ ID NO: 2 , an immunogenic composition and a kit comprising the polypeptide SEQ ID NO: 2 does not reasonably provide enablement for immunogenic composition or kit comprising variants/fragments of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons set for th below:

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the relative skill of those in the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

1-2 .Breadth of the claims and the nature of the invention.

In regards to the polypeptide of the invention and the breadth of the claims the broadest interpretation that applies is variants / fragments of SEQ.ID.NO:2
The claimed invention relates to group a Streptococcus, S.pyogenes polypeptide, SHB-GAS-102, SEQ.ID.NO:2. Streptococcus are gram positive bacteria, which are differentiated by
group specific carbohydrate antigens A through O and said antigens are found at the cell surface. S. pyogenes isolates are distinguished by type-specific M protein antigens. M proteins are important virulence factors which are highly variable both in molecular weights and in sequences. Indeed, more than I00-M protein types have been identified" on the basis of antigenic differences. S. pyogenes SHB-GAS-102 gene was cloned from genomic DNA of serotype M1 S. pyogenes Strain ATCC700294. SHB-GAS-102 gene encodes a 178 amino-acid residues polypeptide with a predicted pI of 9.55 and a predicted molecular mass of 19,431.0 Da.

3-4. The state of prior art and the level of predictability in the art.

The distribution of the SHB-GAS-102 polypeptide among S.pyogenes isolates was tested by immunoblot analysis using pooled mouse anti-SHB-GAS-102 sera. the sera recognized a collection of 13 strains of S. pyogenes representing 13 M serotypes (see Table 3) 1, 2, 3, 4, 5, 6 ,11, 12, 18, 22, 28, 58 and 77. SHB-GAS-102 elected specific antibodies and found to protect mice against Type 3, S.pyogenes. However, variants/fragments of SEQ.ID.NO:2 have not yet been characterized. The specification and the claim do not provide any guidance what changes can or can not be made in SHB-GAS-102. For example, Lederman et al (Molecular Immunology 28:1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Li et al (Proc. Natl. Acad. Sci. USA 77:3211-3214, 1980) disclose that dissociation of immunoreactivity from other activities when constructing analogs (see entire document). Further, the teachings of the Kokolus et al, U.S. Patent 5,807,978 (see column 4) indicate that the ability of a given oligopeptide to elicit antibody responses that cross-react with the native molecule currently is unpredictable. One reason is that oligopeptides only have the ability to represent linear or "continuous" epitope. "Discontinuous" epitope are composed of sequences from

throughout an antigen and rely on folding of the protein to bring the sequences into close proximity of one another. Clearly, oligopeptides are incapable of representing such epitope. Although continuous epitope are structurally less complicated than discontinuous ones, a poor understanding of how the immune system recognizes and responds to these antigenic species is not predictable.

With respect to antigenicity or immunogenicity Holmes, Exp. Opin.Invest. Drugs, 2001, 10(3):511-519) teaches that rabbits were immunized with synthetic peptides which in each case generated high anti-peptide specific immunoreactivity , however, none of the antibodies exhibited binding to the full length antigen. The author concludes that 'Presumably, expression of these epitopes in the context of the protein was important and affected the antibody binding ability' (p. 513, col 1).

5. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

6-7. the amount of guidance present and the existence of working examples.

The applicant has not provided guidance for making and using variants or fragments. The specification provides guidance how to make an isolated comprising the amino acid sequence set forth as SEQ.ID.NO: 2The specification is totally silent in regards to variants/ fragments of SEQ ID NO: 2 that induce an immune response against S.pyogenes.

8. The quantity of experimentation necessary.

The amount of experimentation that is required is undue: while making recombinant polypeptide SEQ.ID.NO: 2 is routine, making and using variants/fragments of SEQ ID NO: 2 against S.pyogenes is not routine and requires more experimentation. Therefore, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

It must be noted that the issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The Applicants make and test position is inconsistent with the decisions of In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "... scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See In re Wands, 858 F.2d at 737, 8 USPQZd at 1404 (Fed. Cir. 1988). Therefore, for the instant specification to be enabling, it needs to provide direction/guidance regarding an acceptable number of different variants/fragments of SEQ.ID.NO:89. Absent sufficient guidance/direction one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and insufficient working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to test all the different type of variants/ fragments of SEQ ID NO:2 encompassed by the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Applicant argues 7/21/09 that a person skilled in the art knows how to make fragments without loss of function and cites several references Applicant also argues that the references cited by the examiner fail to reflect the predictability associated with identifying functional polypeptide variants.

Applicants arguments are fully considered but has not been found persuasive because none of the cited art indicate that the antibodies generated to a chimeric polypeptide (i.e., fragments of polypeptide that are linked) will bind to full length SEQ ID NO:2/ SHB-GAS 102 and induce an immune response against S. pyogenes . Here , the issue is whether or not chimeric polypeptide induces an antibody which can recognize and bind to the full length polypeptide and at the same time immune response against S. pyogenes. The cited references by the examiner in the previous Office action indicated that it is not predictable to induce an antibody against fragment that can bind to the full length polypeptide . Since these antibodies have not been shown bind to the polypeptide , one skilled in the art understands that the antibodies are not immunoreactive and is unpredictable to use them in an immunogenic composition that induces immune response against S. pyogenes . In view of applicant's specification and the prior art cited by the examiner and applicant, it would require undue experimentation on the part of the skilled artisan to use the broadly claimed composition ans kit.

7. The rejection of claims 23, 36, and 38-42 under 35 U.S.C. 102(b) as being anticipated by Telford J et al WO200234771 is maintained for the same reasons as set forth in the previous Office action

Applicant 7/21/09 argues that Telford fails to teach or suggest an imminogenic composition and a kit as claimed because the cited reference teaches hundreds of full-length polypeptides and the polypeptide as claimed.
Applicants arguments are fully considered but has not been found persuasive because Telford et al clearly disclose a polypeptide , SEQ.ID.NO:6346 which is 100% identical to the claimed polypeptide in addition to several hundreds of full-length polypeptides that induce an immune response to S.pyogenes because the polypeptide is obtained from S.pyogenes.

Applicant states that Telford provides more than 5,000 open reading frames that putatively encode polypeptides that are expressed by S. pyogenes and provides no more than a generalized statement with respect to how the various putatively encoded polypeptides disclosed therein may be used. Telford describes that each and every one of the polypeptides disclosed therein may be a useful antigen for a vaccine or a diagnostic. Given that only a few S. pyogenes antigens have been investigated as viable vaccine candidates (see,

e.g., specification at page 1, line 30 through page 2, line 20), a person skilled in the microbiology and vaccine arts would immediately understand that the statement in Telford provides no guidance with respect to which polypeptides disclosed therein may be capable of inducing an immune response against S. pyogenes.

Applicants arguments are fully considered but has not been found persuasive because Telford provides more than 5,000 polypeptides with structure . One such polypeptide was SEQ.ID.NO:6346 (Example 2053, page 2320 in the patent) that can be used for vaccine purposes. Given that the prior art fully discloses the polypeptide from S.pyogenes, one skilled in the microbiology and immunology art knows how to formulate the immunogenic composition comprising said polypeptide to induce an immune response. Again , products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

8. No claims are allowed.

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 1989. The Right Fax number is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272 0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,
/Padma Baskar /
Examiner, Art Unit 1645